Dkt. 0575/54205-A-PCT-US/JPW/AJM/MMI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

plicants : John O'Connor et al.

Serial No.: 09/630,215 Examiner: Gailene Gabel

Filed: August 1, 2000 Group Art Unit: 1641

For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN A

SUBJECT BY hCG ASSAY

1185 Avenue of the Americas New York, NY 10036 July 24, 2003

Commissioner for Patents P.O. Box 1450
Alexandria VA 22313-1450

RECEIVED

JUL 2 9 2003

Sir:

TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, applicants request that the following disclosures be made of record in the above-identified application pursuant to 37 C.F.R. \$1.97(c). These items are also listed on the attached Form PTO-1449 (Exhibit A). Copies of these items are attached hereto as Exhibits 1-4, respectively.

- 1. European Search Report (supplemental) dated April 10,
 2003 (Exhibit 1);
- 2. Huang, S. et al. (1988) "A chromatofocusing study of human chorionic gonadotropin in biological fluids in normal pregnancy, pre-eclampsia and choriocarcinoma," J. Formos Med. Assoc. 87:1036-44 (Exhibit 2);
- 3. Kovalevskaya, G. et al. (2002) "Differential expression of human chorionic gonadotropin (hCG) glycosylation isoforms in failing and continuing pregnancies: preliminary characterization of the hyperglycosylated

Applicants: John O'Connor et al.

Serial No.: 09/630,215 Filed: August 1, 2000

Page 2

hCG epitope," J. Endocrinology 172:497-506 (Exhibit 3); and

4. Rau, B. et al. (1995) "Significance of beta-hCG in the serum as a tumor marker for gastric cancer," Langenbecks Arch. Cher. 380:359-64 (Exhibit 4).

On April 10, 2003, a supplemental European Search Report was issued in connection with European Patent Application No. 99925541.7, PCT International based on Application PCT/US99/02289 which is related to the subject application, citing references 2-4 above. A copy of the April 25, 2003 EPO Communication forwarding the April 10, 2003 supplemental Search Report is attached hereto as Exhibit 1. The search report also lists Wilcox et al., Berger et al., O'Connor et al., and PCT International Publication No. WO 00/70094, which were previously disclosed in the subject application.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Alan J. Morrison Date
Reg. No. 37,399

Respectfully submitted,

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

\7	<u>አ</u>	4.5	8/		_			Page I o	<u>t I</u>	
Form PTO-1449/RADEMED.S. Department of Commerce Patent and Trademark Office							0575/54205	Atty. Docket No. Serial No. 0575/54205-A-PCT-US/ JPW/AJM/MML 09/630,2		
	IN	FORM	1AT	ION DI	ISCLOSURE C	ITATION	Applicant	s: John F. O'Co	nnor et al.	
(Use several sheets if necessary)							Filing Date August 1,	Group 1641		
					U.S. PA	TENT DOCUMENTS	- }			
Examiner Initial	Docu	ment N	umbe	er	Date	Name	Class	Subclass	Filing Date if Appropriate	
			_					ļ		-
			<u> </u>						ļ	
<u> </u>		_	+-	<u> </u>	-					
<u> </u>			<u> </u>	<u> </u>			<u> </u>	<u> </u>	<u> </u>	,
<u> </u>	L					PATENT DOCUMEN				
	Document Number			mber	Date	Country	Class	Subclass	Translation	
								REC	ĔĨVE	D
		\bot						1111	2 9 200	
		-	↓					JUL	2 3 240	
<u> </u>					 			TECH CEN	TER 160	n/2an
<u> </u>			<u></u>						iji Liti Top	UILUU
	Fire					ing Author, Title, Dat supplementa			200	3:
	Eu.	<u>- ope</u>	an	Jear	.cn keport	. (Suppremente	ii) daced	mpili id	, 200.	
- 	Hua	ang,	S.	. et	al. (1988) "A chromato	ofocusing	study of	humaı	n
	cho	chorionic gonadotropin in biological fluids in normal pregnancy, pre-eclampsia and choriocarcinoma," J. Formos								
	1-	_	_	_	-		carcinon	na," J. Fo	rmos	
	Мес	<u>1. A</u>	SSC	oc. 8	37:1036-44	;				
	Ko	<u> </u>	vs)	kava.	G. et al	. (2002) "Dif	ferentia	al express	sion o	 f
						tropin (hCG)				
						pregnancies:			,,	
						e hyperglycos	sylated h	nCG epitor	be," J	•
	Enc	1001	T110	orogy	172:497-	-306;	 	·-·-		
	Rai	 』, B	. 6	et al	. (1995)	"Significance	of beta	a-hCG in t	he se	rum
						gastric cance				
	Che	∍r.	380	0:359	9-64;				·	
						·····				
					,		_			
EXAMINER					DATE CONS	IDERED				
						on is in conformance with !		line through citation	on if not in	
						next communication to appl				